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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,440	05/08/2007	Karl F. Johnson	1096/0011US1	7672
32260	7590	10/15/2010		
NADA JAIN, P.C. 560 White Plains Road, Suite 460 Tarrytown, NY 10591			EXAMINER BURKHART, MICHAEL D	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 10/15/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/585,440

Applicant(s)

JOHNSON ET AL.

Examiner

Michael Burkhardt

Art Unit

1633

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1, 7, 11, 20, 21 and 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 8-10, 12-19, 22-26 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt and entry of the amendment dated 8/2/2010 is acknowledged. After entry of the amendment, claims 1-35 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Objections

Claims 10 and 35 are objected to because of the following informalities: the claim recite non-elected subject matter, i.e. the pcWin1 vector of Group I. Appropriate correction is required.

Claim 16 is objected to because of the following informalities: "said protein into-nucleic acid vector" in line 2 should be "into a nucleic acid vector." Appropriate correction is required.

Claim 26 is objected to because of the following informalities: the claim has been amended, without any amendment markings, to recite "The pcWIN280P expression vector" in line 1, which should be "The pcWIN2/MBP expression vector" as originally claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by amendment of the claim.**

Claim 26 recites the limitation "The pcWIN280P expression vector" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 2-6, 8-10, 12-19, 22-26 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for reasons made of record in the Office Action dated 4/1/2010, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 8/2/2010 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) the specification indicates one source of pCWori, and additional and numerous sources are found in the scientific literature, and a variant is commercially available; 2) the instant specification provides detailed teachings regarding the preparation of the pCWin2 vector(s) from the pCWori plasmid.

Regarding 1), mention of a potential source of a biological material necessary to the claimed subject matter in the specification does not satisfy the 35 USC 112 requirement. There is no guarantee that the pCWori plasmid will be made available to the public from the source applicant used, nor that such a source will be available throughout the enforceable life of any

patent issued on the instant claims. The various laboratories and scientific personnel found in the references cited by applicants no doubt at one time used the pCWori plasmid, but, there is no evidence that such organizations still possess the plasmid, nor that they would furnish the public with said plasmid upon request at the present time, or throughout the term of any patent issued from the instant claims. These institutions are under no obligation to maintain the plasmid or provide it to the public upon request. Likewise, there is no indication or guarantee that the commercial source will continue to provide the pCWori variant throughout the term of any patent granted to the instant claims, nor that the commercially available variant is suitable for use in the preparation of the instantly claimed pCWin2 vectors.

Regarding 2), this is not in dispute and was mentioned in the previous Office Action. However, this does not remedy the basis for this rejection for reason of record and for reason set forth above. It is noted a deposit of the pCWin2 vector itself would also satisfy the requirements of 35 USC 112 -1st ¶ if the pCWori plasmid is difficult to deposit.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633